Fluoridex® 0.63% Stannous Fluoride Rinse

**INDICATIONS AND USAGE**

It is well established that a 0.1% stannous fluoride rinse is a convenient way to apply fluoride to the surfaces of teeth to aid in the prevention of decalcification and dental caries. This is accomplished by increasing the resistance of tooth surfaces to acid dissolution.

**DOSEAGE AND ADMINISTRATION**

Adults and pediatric patients 12 years and older, use once a day or more often as directed by a dentist, following regular brushing and flossing. Pour the concentrated Fluoridex Stannous Fluoride Rinse to the 1/8 fl. oz. mark in the mixing cup (to the bottom mark). Add water to the 1 fl. oz. line and mix. This prepares a 0.1% stannous fluoride rinse. Use immediately after preparing the rinse. Place one half of the solution into the mouth and vigorously swish for one minute, then expectorate. Repeat the one-minute treatment with the remaining rinse. Do NOT SWALLOW the rinse. Pediatric patients under 12 years of age should be supervised in the use of this product to help minimize swallowing. For pediatric patients under 6 years of age, consult a dentist or physician.

**DOSEAGE FORMS AND STRENGTHS**

Translucent – clear viscous liquid containing 0.63% Stannous Fluoride (Mint).

**CONTRAINDICATIONS**

None (may be used whether drinking water is fluoridated or not, since topical fluoride cannot produce fluorosis).

**WARNINGS AND PRECAUTIONS**

Warnings: As with all medications, keep out of reach of infants and children. Do not use before mixing with water. Read the directions carefully. Pediatric patients under 12 years of age should be supervised in the use of this product. For pediatric patients under 6 years of age, consult a dentist or physician. This product may produce temporary surface staining of teeth. Adequate brushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.

Precautions: DO NOT SWALLOW.

**ADVERSE REACTIONS**

Allergic reactions and other idiosyncrasies have rarely been reported.

To report SUSPECTED ADVERSE REACTIONS, contact DenMat at consumer@denmat.com
CONTRAINDICATIONS

For pediatric patients under 6 years of age, do not use without consulting a dentist or physician.

Pediatric patients under 12 years of age should be supervised in the use of this product.

Repeat the one-minute treatment with the remaining solution and expectorate.

Use immediately after preparing the rinse. Place one half of the solution into the mouth and vigorously swish for one (1) minute, then expectorate (spit out).

DO NOT SWALLOW the rinse.

DO NOT use before mixing with water.

Use as directed by a dental professional.

Read directions carefully before using.

Pediatric patients under 12 years of age should be supervised in the use of this product.

For pediatric patients under 6 years of age, consult a dentist or physician.

This product may produce temporary surface staining of teeth. Adequate brushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.

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Allergic reactions and other idiosyncrasies are rarely reported.

USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category B

It has been shown that fluoride crosses the placenta of rats, but only 0.01% of the amount administered is incorporated in fetal tissues. Animal studies (rats, mice, rabbits) have shown that fluoride is not a teratogen. Maternal exposure to 12.2 mg fluoride/kg of body weight (rats) or 13.1 mg/kg of body weight (rabbits) did not affect the litter size or fetal weight and did not increase the frequency of skeletal or visceral malformations.

There are no adequate or well-controlled clinical studies in pregnant women. However, epidemiological studies conducted in areas with high levels of naturally fluoridated water showed no increase in birth defects. Heavy exposure to fluoride during in utero development may result in skeletal fluorosis which becomes evident in childhood.

8.2 Nursing Mothers

It is not known if fluoride is excreted in human milk. However, many drugs are excreted in milk, and caution should be exercised when products containing fluoride are administered to a nursing woman. Reduced milk production was reported in farm-raised fox when the animals were fed a diet containing a high concentration of fluoride (98-137 mg/kg of body weight). No adverse effects on parturition, lactation, or offspring were seen in rats administered fluoride up to 5mg/kg of body weight.

OVERDOSAGE

Accidental ingestion of a usual treatment dose (3.7 ml or 1/8 fl. oz.) is not harmful. Treat with milk or antacids. Accidental ingestion of large amounts of fluoride may result in acute burning in the mouth and sore tongue. Nausea, vomiting, and diarrhea may occur soon after ingestion (within 30 minutes) and are accompanied by salivation, hematemesis and epigastric cramping abdominal pain. These symptoms may persist for 24 hours. If less than 5mg fluoride/kg body weight (i.e., less than 2.3 mg fluoride/lb body weight) have been ingested, give calcium (e.g., milk orally to relieve gastrointestinal symptoms and observe for a few hours. If more than 5mg fluoride/kg body weight (i.e., more than 2.3 mg fluoride/lb body weight) have been ingested, induce vomiting, give soluble calcium orally (e.g., milk, 5% calcium gluconate or calcium lactate solution) and immediately seek medical assistance. For accidental ingestion of more than 15 mg fluoride/kg body weight (i.e., more than 6.9 mg fluoride/lb body weight), induce vomiting and admit immediately to a hospital facility.